Peter W. Burg Seth A. Katz

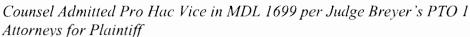
BURG SIMPSON ELDREDGE HERSH & JARDINE, PC

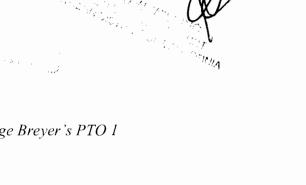
Defendant

40 Inverness Drive East Englewood, CO 80112

Telephone: (303) 792-5595 Facsimile: (303) 708-0527

Joseph H. Saunders SAUNDERS & WALKER, P.A. 3491 Gandy Blvd., Suite 200 Pinellas Park, FL 33781 Telephone: (727) 579-4500





# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA (SAN FRANCISCO DIVISION)

CRB

IN RE BEXTRA AND CELEBREX	Master Docket No.: M:05-CV-01699-CRB
MARKETING SALES PRACTICES AND	MDI NI 1700
PRODUCTS LIABILITY LITIGATION	MDL No.: 1699
MARY SHAW,	CasCy 07 5951
/ Plaintiff,	CIVIL COMPLAINT FOR DAMAGES
V.	JURY TRIAL DEMANDED
PFIZER, INC.,	

**COMES NOW** the Plaintiff, Mary Shaw, and for cause of action would respectfully show to the Court and the jury the following:

1. This is a civil action brought on behalf of Plaintiff who suffered a heart attack as a result of the ingestion of BEXTRA. Plaintiff Mary Shaw ingested BEXTRA daily from October 4, 2004 to March 16, 2005, and suffered a severe myocardial infarction on January 9, 2005.

#### **PARTIES**

- 2. Plaintiff is an individual citizen of the State of New York and a resident of Niagra Falls, New York. At the time of her injury, Plaintiff was an individual citizen of the state of South Carolina, and a resident of Conway, South Carolina.
- 3. Defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation, authorized to do and doing business in the State of South Carolina, with its principal place of business in New York, has committed a tort within the State of South Carolina and may be served with process of this Court in accordance with *Federal Rules of Civil Procedure*, Rule 4(h), through its registered agent for service of process.
- 4. Defendant Pfizer is liable for the acts and omissions of its predecessors in interest, Searle and Pharmacia.
- G.D. Searle was the discoverer and developer of BEXTRA. In 1999 Searle and
   Pfizer joined forces to promote BEXTRA.
- 6. Thereafter, Pharmacia acquired Searle in 2000, and Pharmacia then merged with Pfizer on April 16, 2003.

- 7. When Pharmacia acquired Searle, it acquired not only the rights and benefits of Searle's business and products, but also the liabilities associated with that business and those products.
- 8. When Pfizer merged with Pharmacia, Pfizer acquired all of Pharmacia's liabilities.

### **JURISDICTION AND VENUE**

- 9. This Honorable Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, inasmuch as the parties are citizens of different states, and the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000), exclusive of interest and costs.
- 10. Venue is proper in this District pursuant to 28 U.S.C. §1391. Defendant marketed, advertised and distributed this dangerous product in this district, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this district, and reside in this district under 28 U.S.C. §1391(c), such that venue is proper.

#### **FACTUAL ALLEGATIONS**

11. Pfizer is in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling its product valdecoxib under the trade name of BEXTRA. Pfizer, at all times relevant hereto, designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold BEXTRA in the States of South Carolina and New York.

- 12. Plaintiff Mary Shaw was first prescribed BEXTRA on October 4, 2004. Plaintiff used BEXTRA continually until March 16, 2005, at which time her physician told her to discontinue use because it was not helping manage the pain that she was suffering due to degenerative joint disease.
- 13. Plaintiff Mary Shaw ingested BEXTRA as prescribed and, as a result thereof, suffered a myocardial infarction on January 9, 2005.
- 14. Plaintiff was initially revived from her myocardial infarction by a cardiac defibrillator. Shortly thereafter, doctors placed two stents in her heart. She has also been forced to take prescription medication as a result of her injury to reduce the risk of suffering another myocardial infarction.
- 15. At the time of her injury, Plaintiff was living with her husband on four acres of land in South Carolina. Afterwards, however, Plaintiff required more assistance with daily tasks than she had needed before, and she also became concerned about living isolated from emergency help. As a direct result of her myocardial infarction, Plaintiff and her husband sold their longtime home and moved to Niagra Falls, NY so that she could be closer to family who would be able to assist her with the daily tasks she could no longer complete independently.
- 16. At all times relevant herein, Plaintiff Mary Shaw was unaware of the serious side effects and dangerous properties of the drug as set forth herein.
- 17. The product in question was designed, formulated, patented, marketed, sold, tested, warranted, and ultimately distributed by the Defendant as BEXTRA.

- 18. BEXTRA is in a class of drugs called non-steroidal anti-inflammatory drugs ("NSAIDs") with selective cyclooxygenase 2 inhibitory properties ("COX-2 Inhibitor").
- 19. In November 2001, the Food and Drug Administration ("FDA") approved BEXTRA for the treatment and management of symptoms of osteoarthritis and rheumatoid arthritis in adults.
- 20. Prior to April 7, 2005, Pfizer had refused to withdraw BEXTRA from the market, despite its awareness of the numerous scientific studies documenting greater than triple the risk of heart attacks, strokes, and death in connection with the use of BEXTRA.
- 21. As reported in the Wall Street Journal, on or about April 7, 2005, the FDA had to ask Pfizer to pull BEXTRA from the market due to safety concerns with the drug, including heart attacks, strokes, and death suffered by persons such as Plaintiff, Mary Shaw.
- 22. These concerns were also reported in an article in the New England Journal of Medicine, on or about March 17, 2005 based upon Pfizer's own clinical trials, and due in part to the similarity of BEXTRA to other COX-2 inhibitors in its selection of the COX-2 enzyme in the human body.
- 23. Defendant itself was already well aware of the cardiovascular risks associated with BEXTRA, and had been aware at least since before Plaintiff suffered her injuries and losses.

- 24. Defendant materially breached its obligations to consumers, such as Plaintiff Mary Shaw, including, but not limited to, its obligations with respect to the design, testing, manufacturing, warning, marketing, warranting, and sale of BEXTRA.
- 25. Defendant expressly and/or impliedly warranted to the market, including Plaintiff, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials to the health care community, that BEXTRA was safe and effective, and was fit and proper for its intended use.
- 26. Defendant was aware of the substantial risks of taking BEXTRA but failed to fully disclose these risks to the market.
- 27. Defendant failed to meet the applicable standards of care, which were intended for the benefit of individual consumers such as Plaintiff Mary Shaw.
- 28. Despite the fact that Defendant knew or should have known of the serious health risks associated with the use of BEXTRA, Defendant failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.
- 29. Had Plaintiff and/or her health care providers known the risks and dangers associated with BEXTRA, she would not have used BEXTRA and would not have suffered the effects of an acute myocardial infarction.
- 30. Further, as a direct and proximate result of Plaintiff's use of BEXTRA, Plaintiff suffered significant mental anguish and emotional distress, was in fear for her life, and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

- 31. Plaintiff has also incurred medical expenses and economic harm, as a direct and proximate result of her use of BEXTRA.
- 32. At all times relevant herein, Defendant's actions were willful and wanton and in reckless disregard for the safety of others, including Plaintiff.

#### FRAUDULENT CONCEALMENT

- 33. Defendant knew that BEXTRA did not have as favorable a safety profile as other pain relief medications available on the market and that users of BEXTRA would be at increased risk for heart attacks or strokes.
- 34. Defendant intentionally concealed this information from the medical community and the consuming public to preserve the profits they were earning from BEXTRA.
- 35. As a result of Defendant's concealment of this material information, neither the medical community nor the consuming public knew of the risks associated with BEXTRA.
- 36. Defendant's actions in concealing the true risk associated with BEXTRA until April 2005 results in an equitable tolling of the statute of limitations.

# FIRST CAUSE OF ACTION Strict Products Liability Defective Design

- 37. Plaintiff adopts and realleges all paragraphs above as if fully set forth herein.
- 38. Defendant is the manufacturer, designer, distributor, seller, or supplier of BEXTRA.

- 39. BEXTRA, as designed, manufactured, sold and/or supplied by Defendant Pfizer, was placed into the stream of commerce by Defendant in a defective and unreasonably dangerous condition taking into consideration the utility of the product and the risks involved with its use.
- 40. Plaintiff alleges that BEXTRA was defective in design and/or formulation in that, when it left the hands of Defendant and/or its representatives, agents or assignees, the foreseeable risks of serious harm posed by this drug far exceeded its benefits. The foreseeable risks of serious harm were such that Plaintiff, if she had known of such foreseeable risks and alleged benefits, would not have ingested BEXTRA.
- 41. When placed into the stream of commerce, the drug was defective in design and formulation, making its use more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with pain management, in that it was capable of causing cardiovascular injuries, including heart attacks.
- 42. Safer alternative designs for pain relief existed at the time that Defendant manufactured, marketed and sold BEXTRA and at the time that Plaintiff Mary Shaw used BEXTRA, including numerous other pain relievers that were on the market at the same time as BEXTRA.
- 43. Notwithstanding the foregoing, Defendant continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of pain relief available.

44. Had Plaintiff and/or her heath care providers known the risks and dangers associated with BEXTRA, she would not have used BEXTRA and would not have suffered the effects of a myocardial infarction.

Document 1

As a direct and proximate result of Pfizer's conscious and deliberate disregard for 45. the rights and safety of consumers such as Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff endured substantial pain and suffering. She incurred significant expenses for medical care and treatment. Plaintiff suffered economic loss, and was otherwise physically, emotionally and economically injured. Plaintiff's injuries and damages were permanent and continued throughout the remainder of her life.

#### SECOND CAUSE OF ACTION

## **Strict Products Liability Defect Due to Inadequate Warnings**

- Plaintiff adopts and realleges all paragraphs above as if fully set forth herein. 46.
- 47. BEXTRA, as designed, manufactured, distributed, sold and/or supplied by Defendant, was defective in marketing due to inadequate warnings, instructions and/or labeling because Defendant knew or should have known that the product created significant risks of serious bodily harm and death to consumers and it failed to adequately warn consumers and/or their health care providers of such risks.
- 48. BEXTRA was also defective due to inadequate warnings and misrepresentations to healthcare professionals. Defendant knew that had healthcare professionals been adequately warned of the serious risks of injury to their patients, healthcare professionals would not have prescribed BEXTRA to their patients.

9

- 49. Had Plaintiff and/or her healthcare providers known the risks and dangers associated with BEXTRA, she would not have used BEXTRA and would not have suffered the effects of a myocardial infarction.
- 50. As a direct and proximate result of Pfizer's conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff endured substantial pain and suffering. She incurred significant expenses for medical care and treatment. Plaintiff suffered economic loss, and was otherwise physically, emotionally and economically injured. Plaintiff's injuries and damages were permanent and continued throughout the remainder of her life.

#### THIRD CAUSE OF ACTION

# Strict Products Liability Defect Due to Failure to Conduct Adequate Testing

- 51. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein.
- 52. BEXTRA, as designed, manufactured, distributed, sold and/or supplied by Defendant, was defective due to inadequate testing.
- 53. BEXTRA was also defective due to inadequate testing both before and after Defendant became aware of the risks of ingesting the drug.
- 54. As the producing and direct cause and legal result of the design defect and/or the marketing defect due to the Defendant's failure to warn consumers, as well as the defective condition of the drug manufactured and supplied by Defendant and its representatives, Plaintiff Mary Shaw suffered injuries and monetary damages.

#### **FOURTH CAUSE OF ACTION**

#### Fraud

- 56. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein, and further alleges:
- 57. Defendant Pfizer fraudulently represented to the general public, as well as to healthcare professionals, that BEXTRA was a safe and effective drug. Defendant Pfizer made the representation while knowing that, if healthcare professionals knew the truth about the serious nature of the risks associated with the ingestion of BEXTRA, they would not prescribe this drug.
- 58. Defendant knew its representations to be false, and Plaintiff Mary Shaw relied on Defendant's false representations in her ingestion of BEXTRA. These fraudulent representations by Defendant were a proximate cause of the injuries to and monetary losses of Plaintiff Mary Shaw.
- 59. Had Plaintiff and/or her healthcare providers known the risks and dangers associated with BEXTRA, she would not have used BEXTRA and would not have suffered the effects of a myocardial infarction.

#### FIFTH CAUSE OF ACTION

#### Negligence

60. Plaintiff adopts and realleges all foregoing paragraphs of as if fully set forth herein, and further alleges:

- 61. Defendant Pfizer and its representatives were merchants or sellers of BEXTRA. Defendant Pfizer had a duty to exercise reasonable care in the design, manufacturing, marketing, sale, testing and/or distribution of this drug into the stream of commerce.
- 62. Defendant Pfizer failed to exercise ordinary care in the design, manufacturing, marketing, sale, testing, and/or distribution of BEXTRA into interstate commerce. Defendant knew or should have known that BEXTRA greatly increased Plaintiff's risks of having a heart attack and/or stroke, or worse, of causing her death.
- 63. Despite the fact that Defendant knew or should have known that BEXTRA could cause unreasonably injurious results and/or death to Plaintiff, Defendant continued to market, distribute, and sell BEXTRA to the public.
- 64. Defendant Pfizer knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injuries and/or death as a result of Defendant Pfizer's failure to exercise ordinary care as described above. Moreover, after Defendant became aware of the serious risks of ingesting BEXTRA, it owed a legal duty to the public in general, and to Plaintiff in particular, to disclose this knowledge.
- 65. Defendant Pfizer's breach of its duty to disclose this information was a proximate cause of the Plaintiff's injuries and monetary damages.

#### SIXTH CAUSE OF ACTION

#### **Negligent Misrepresentations**

66. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein, and further alleges:

- 67. Defendant Pfizer represented and marketed BEXTRA as being safe and effective. After Defendant became aware of the risk of ingesting BEXTRA, however, Defendant failed to communicate to Plaintiff and/or the public at large, that the ingestion of this drug could cause a person to suffer a heart attack or stroke, or that BEXTRA could cause death.
- 68. Therefore, Plaintiff brings this cause of action against Defendant Pfizer under the theory of negligent misrepresentation for the following reasons:
  - a. Defendant failed to warn Plaintiff, and other consumers, of the defective condition of BEXTRA as manufactured and/or supplied by Defendant; and
  - b. Defendant Pfizer, individually, and through its agents, representatives, distributors, and/or employees, negligently misrepresented material facts about BEXTRA in that they made misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendant Pfizer made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations; and
  - c. The above misrepresentations were made to the Plaintiff as well as to the public in general; and
  - d. Plaintiff Mary Shaw and her healthcare provider justifiably relied on Defendant's misrepresentations to their detriment; and
  - e. Consequently, Plaintiff Mary Shaw's ingestion of BEXTRA proximately caused her injuries and monetary losses.

#### **SEVENTH CAUSE OF ACTION**

#### **Expressed Warranty for Goods**

- 69. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein, and further alleges:
- 70. Defendant Pfizer breached its express warranty of goods. Defendant was a merchant and/or seller of BEXTRA, and sold this drug to consumers for the ordinary purpose for which the drug is used. Defendant owed a legal duty to Plaintiff, and to the public in general, to disclose its knowledge of the serious risks of ingesting BEXTRA as marketed.
- 71. This breach of duty was a proximate cause of the injuries and monetary loss of Plaintiff.

#### **EIGHTH CAUSE OF ACTION**

#### **Implied Warranty of Merchantibility**

- 72. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein, and further alleges:
- 73. Defendant Pfizer breached its implied warranty of merchantibility. Defendant was a merchant and/or seller of BEXTRA, and sold this drug to Plaintiff and other consumers for the ordinary purpose for which the drug is used.
- 74. BEXTRA was defective, unmerchantable, and unfit for the ordinary purposes for which such drugs are used, and as such, was a proximate cause of Plaintiff's injuries and monetary losses.

#### **NINTH CAUSE OF ACTION**

#### Implied Warranty of Fitness for a Particular Purpose

- 75. Plaintiff adopts and realleges all foregoing paragraphs as if fully set forth herein and further alleges:
- 76. Defendant Pfizer breached its implied warranty of fitness. Defendant sold BEXTRA, and, at the time of the sale of this drug, Defendant knew or had a reason to know of a particular purpose for which this drug was to be used, namely, in the treatment of osteoarthritis and rheumatoid arthritis.
- 77. At the time of the sale of the drug to Plaintiff, Defendant knew or had reason to know that Plaintiff was relying on the skill and judgment of Defendant Pfizer to furnish a suitable product for the intended purpose. At the time of the sale of the drug to Plaintiff, Defendant Pfizer exercised its skill and judgment in the selection of this drug as safe and effective, and Plaintiff relied thereon.
- 78. BEXTRA was not reasonably fit and/or suitable for the use for which it was selected. Defendant's failure to select and sell a product which was reasonably safe for its intended purpose proximately caused Plaintiff's injuries and monetary losses.

#### TENTH CAUSE OF ACTION

#### Unlawful and Deceptive Business Practices in Violation of 815 ILCS 505

79. Defendant Pfizer is the manufacturer of BEXTRA and is in the business of designing, manufacturing, marketing, developing testing, labeling, promoting, distributing, warranting, and selling its product BEXTRA to consumers, including Plaintiff herein.

- 80. At all times relevant herein, Plaintiff Mary Shaw was unaware of the serious side effects and dangerous properties of the drug as set forth herein.
- 81. At the time of the sale of the drug to Plaintiff, Defendant knew or had reason to know that Plaintiff was relying on the skill and judgment of Defendant Pfizer to furnish a suitable product for the intended purpose.
- 82. At the time of the sale of the drug to Plaintiff, Defendant Pfizer exercised its skill and judgment in the selection of this drug as safe and effective, and Plaintiff relied thereon.
- 83. Defendant was aware of the substantial risks of taking BEXTRA but failed to fully disclose these risks to the market, including Plaintiff and her health care providers, and had been aware of those risks at least since before Plaintiff suffered her injuries and losses.
- 84. Defendant knowingly made false representations as to the safety characteristics and risks associated with its drug BEXTRA.
- 85. As a direct and proximate result of Pfizer's conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff endured substantial pain and suffering. She incurred significant expenses for medical care and treatment. Plaintiff suffered economic loss, and was otherwise physically, emotionally and economically injured. Plaintiff's injuries and damages were permanent and continued throughout her life.

#### **PUNITIVE DAMAGES**

86. At all times relevant hereto, Defendant Pfizer actually knew of the defective nature of BEXTRA as set forth herein, and yet continued to design, manufacture, market,

distribute, and sell BEXTRA so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable harm caused by BEXTRA. Defendant Pfizer's conduct exhibits such a lack of care as to establish that its actions were the result of fraud, ill will, recklessness, and/or willful and intentional disregard for the safety and rights of Plaintiff as well as the general public. Plaintiff is therefore entitled to punitive damages for such conduct.

#### **JURY DEMAND**

87. Plaintiff hereby demands a trial by jury on all issues in this case.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that upon trial hereof, the Court grant her the following:

- a. Judgment against Defendant Pfizer for actual damages, as set forth above, in an amount in excess of the minimum jurisdictional limits of this Honorable Court; and
- b. Interest on said Judgment, at the legal rate from the date of the Judgment; and
- c. Plaintiff's costs of this suit; and
- d. Damages for pain and anguish, as set forth above, in an amount to be determined upon proof at trial; and
- e. Medical expenses; and
- f. Prejudgment interest as allowed by law; and
- g. Punitive damages in an amount to be determined upon proof at trial; and
- h. Any additional and further relief as this Court deems just and proper.

Respectfully submitted,

BURG SIMSPON FÆDREDGE HERSH & JARDINE D.C.

Peter W. Burg Seth A. Katz 40 Inverness Drive East Englewood, CO 80112 Telephone: (§03) 792-5595

Fax: (303) 708-0527

Joseph H. Saunders SAUNDERS & WALKER, P.A. 3491 Gandy Blvd., Suite 200 Pinellas Park, FL 33781 Telephone: (727) 579-4500

Attorneys for Plaintiff Mary Shaw Counsel Admitted Pro Hac Vice in MDL 1699 per Judge Breyer's PTO 1